

and injury. **Conclusion:** LMWH given systemically or locally, with or without iontophoresis did not limit neointimal thickness in this stent model. This result suggest that clinical trials of LMWH may be similarly negative.

973-63 Predictors of Target Vessel Revascularization Following Coronary Stent Deployment

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Objective: We sought to determine the clinical, angiographic and ultrasound predictors of target vessel revascularization (TVR) after coronary stenting.

Methods: All patients who underwent ultrasound-guided 1 or 2 stent implantation over a 14 month period were included in this study. Clinical and angiographic data were prospectively collected in a dedicated database. Intravascular ultrasound analysis of the stented segments was performed in a core laboratory. Patients were followed for TVR over 8.0 ± 2.4 months.

Results: Of 239 consecutive study patients, TVR was performed in 32 (13%). No clinical characteristics or risk factors were predictive of TVR. The effects of other variables on the probability of TVR follows:

	Odds Ratio (Per 1 SD)	95% C.I.
Angiographic Variables		
Decreasing reference diameter	1.6	1.1-2.6
Increasing baseline % diameter stenosis	1.7	1.1-2.5
Increasing baseline lesion length	1.5	1.1-2.5
Distal flow at baseline <TIMI 3	5.0	1.7-14
Ostial location of lesions	2.9	1.1-7.5
Decreasing final % diameter stenosis	1.2	0.85-1.8
Final Ultrasound Variables		
Decreasing minimum stent lumen diameter	2.1	1.4-3.3
Decreasing minimum stent lumen area	2.2	1.4-3.8
Decreasing final % diameter stenosis	1.1	0.79-1.7
Decreasing final % area stenosis	1.3	0.89-1.9

Conclusions: Pre-intervention angiographic variables, particularly TIMI flow and ostial location, predict TVR. Post-stent percent stenosis by angiography or ultrasound do not impact outcome. However, absolute in-stent lumen area, measured by ultrasound, is an important determinant of TVR.

973-64 Influence of Lesion Length on Late Angiographic Outcome and Restenotic Process After Successful Stent Implantation

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The purpose of the present study was to investigate the influence of lesion length on late angiographic outcome and restenosis process after successful stent placement. The study population comprised 451 consecutive lesions implanted native arteries at elective situation (Palmaz-Schatz stent 401, Cordis stent 50) and satisfactory angiographic analysis before, after stenting and 3 or 6 months follow-up (FUP) in a single center (Feb. 1990-Feb. 1995). Total occlusion at baseline and follow-up were excluded. The patients were divided into 3 groups according to lesion length and following variables were compared.

Lesion length	1) <7.5 mm	2) 7.5-14.9 mm	3) ≥ 15.0 mm	p
No. of lesion	145	255	51	
No. of stent	1.0 \pm 0.2	1.0 \pm 0	1.3 \pm 0.5	< 0.0001
Vessel size (mm)	3.22 \pm 0.58	3.21 \pm 0.54	3.20 \pm 0.65	
MLD pre (mm)	0.94 \pm 0.38	0.83 \pm 0.38	0.77 \pm 0.40	0.006
MLD post (mm)	2.95 \pm 0.38	2.89 \pm 0.42	2.77 \pm 0.51	0.03
Acute gain (mm)	2.01 \pm 0.48	2.06 \pm 0.48	2.00 \pm 0.47	
MLD FUP (mm)	2.15 \pm 0.68	2.06 \pm 0.71	1.80 \pm 0.75	0.009
Late loss (mm)	0.80 \pm 0.60	0.83 \pm 0.59	0.97 \pm 0.75	
Restenosis (50% \leq)	15%	20%	31%	0.01

No: number, MLD: Minimal Lumen Diameter.

Late angiographic outcome such as MLD at follow-up and binary restenosis rate correlated closely with lesion length. Lesion length was found to be exert a significant positive effect on late loss but not in acute gain by univariable and multivariable ($p < 0.001$) analysis. The relative gain/loss relationship within the groups showed that it vary with the lesion length (group 1) r loss = 0.31 r gain = 0.06 , group 2) $y = 0.23x + 0.11$, group 3) $y = 0.48x + 0.01$. In conclusion, lesion length itself influence on both late angiographic outcome and restenosis process. One should be carefully weighed in selection of the patients.

973-65 Are ACC/AHA Lesion Characteristics Predictive for Late Angiographic Results After Coronary Stent Placement?

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ACC/AHA lesion characteristics describe the complexity of stenoses to predict the outcome after PTCA. This retrospective study analyzes the quantitative angiographic 6-month follow-up (FU) of 588 lesions in 529 patients with successful coronary stent placement (p-values as calculated by ANOVA).

	A (n = 30)	B1 (n = 49)	B2 (n = 204)	C (n = 305)	p
MLD pre (mm)	0.86 \pm 0.67	0.79 \pm 0.34	0.60 \pm 0.53	0.68 \pm 0.46	< 0.05
RD pre (mm)	2.98 \pm 0.67	2.96 \pm 0.50	3.08 \pm 0.57	3.04 \pm 0.56	ns
Number of stents	1.3 \pm 0.5	2.5 \pm 2.0	2.6 \pm 1.5	3.0 \pm 1.8	< 0.05
Balloon/vessel	1.10 \pm 0.13	1.12 \pm 0.14	1.11 \pm 0.19	1.15 \pm 0.17	ns
Acute gain (mm)	2.07 \pm 0.54	2.12 \pm 0.53	2.43 \pm 0.65	2.37 \pm 0.62	< 0.05
MLD post (mm)	2.93 \pm 0.56	2.91 \pm 0.46	3.03 \pm 0.50	3.05 \pm 0.53	ns
RD post (mm)	2.98 \pm 0.58	3.05 \pm 0.51	3.17 \pm 0.49	3.17 \pm 0.057	ns
MLD FU (mm)	2.19 \pm 1.00	1.96 \pm 0.80	2.06 \pm 0.92	1.90 \pm 0.91	ns
RD FU (mm)	3.01 \pm 0.61	2.92 \pm 0.57	3.03 \pm 0.54	3.05 \pm 0.56	ns
Late loss (mm)	0.73 \pm 0.80	0.95 \pm 0.83	0.97 \pm 0.81	1.15 \pm 0.83	< 0.05
Restenosis rate	23.3%	20.4%	22.6%	31.8%	ns

Conclusions: The differences in acute data reflect the ACC/AHA grading of stenoses. Late loss is significantly higher in complex stenoses with a trend for higher restenosis rates. These data suggest that lesions of high ACC/AHA-grading also have a poorer long-term angiographic outcome after stenting.

973-66 Long-Term Clinical Outcomes in "Low-Risk" and "High-Risk" Patients Undergoing Coronary Stent Implantation

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Previously we showed that low-risk pts undergoing "optimal" Palmaz-Schatz stent implantation (ultrasound guidance and ≥ 16 atm adjunct PTCA) with reduced anticoagulation (aspirin and ticlopidine only) had excellent acute and long-term outcomes. To determine the outcomes in "high risk" pts, defined as (1) suboptimal implantation (poor apposition or incomplete expansion), (2) ≥ 3 stents, or (3) thrombus @ lesion site (or peri-infarction), treated with extended anticoagulation (aspirin, ticlopidine, and Lovenox[®] for 2 weeks), we assessed early and late (>6-month) clinical events in a consecutive series of 1322 native coronary and SVG Palmaz-Schatz stent pts.

	Native Coronaries		SVG's	
	Low-risk (N = 417)	High-risk (N = 547)	Low-risk (N = 134)	High-risk (N = 224)
MC/SAT (%)	0.7/0.6	0.9/0.2	0.7/0.7	0.9/0.4
TLR (%)	11.7	19.3*	14.3	11.2
Re-PTCA (%)	8.5	13.0*	9.1	7.6
CABG (%)	3.6	7.1*	5.7	4.4

MC = major complications (death, MI, CABG); SAT = subacute thrombosis; TLR = target lesion revascularization; * $p < 0.05$ vs. low-risk group.

In conclusion: After ultrasound guided stent implantation, (1) both low- and high-risk groups had excellent acute outcomes, but (2) high-risk native coronary pts had significantly greater TLR.

973-67 Clinical and Angiographic Restenosis After Coronary Stenting. Incidence and Predictors

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To assess the incidence and predictors of restenosis (R) after coronary stenting (CS), we studied the evolution of 415 stented lesions from 373 consecutive pts (61 \pm 10 yr, 87% male). A total of 469 stents (Palmaz-Schatz: 93% Wiktor: 7%) were implanted (1.13 stent/lesion). In 63% of pts, PTCA was done due to unstable angina. Indications for CS were: restenosis 14%, "bail-out" 31%, suboptimal result 6%, and "de novo" lesions 49%. The left anterior descending artery was the most frequently stented (54%).

Angiographic follow-up (FU) at 6 months was done in 94% of lesions. Clinical FU was completed in 94% of pts. Angiographic R ($> 50\%$ criterion, QCA) occurred in 23% of lesions (CI 95%: 19-28%) but only 35 pts developed angina (clinical R: 11%, CI 95%: 8-15%). Univariate analysis of 33 clinical, angiographic and procedural variables showed that type C lesions ($p = 0.04$), number of stents per lesions ($p = 0.02$), diabetes ($p = 0.02$), minimal luminal

diameter (MLD) pre-PTCA ($p = 0.02$) and MLD post-CS ($p = 0.03$) were related to restenosis. Multivariate analysis (logistic regression) identified the presence of diabetes (odds ratio [OR]: 3.5, CI 95%: 1.4-8.1), number of stents per lesion (OR 3.1, CI 95%: 1.2-7.4) and MLD post-CS (OR 0.3, CI 95%: 0.1-0.6) as independent predictors of R.

Thus: 1) Despite the baseline unfavourable characteristics of this sample, a low rate of clinical and angiographic R after CS was observed; 2) MLD after CS, number of stents per lesion and diabetes were identified as independent predictors of restenosis.

973-68 Quantitative Angiographic Predictors of Restenosis after the Less Shortening Wallstent Implantation

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The mechanism of stent restenosis still remains unknown. To identify the angiographic predictors of stent restenosis, we performed a retrospective analysis in 72 patients with the Wallstent implantation and complete set of quantitative angiographic analysis (pre and post procedure and 6 month follow-up [fup]). Twenty-one patients (29%) had restenosis ($\geq 50\%$ diameter stenosis at fup). Minimal luminal diameter (MLD), lesion length and reference vessel size were measured by QCA system (CAAS II). Proximal reference vessel diameter (prox RD) and distal reference vessel diameter (distal RD) were compared with Wallstent diameter used (WS diam).

	Non-restenosis (51 Patients)	Restenosis (21 patients)	p-value
Lesion Length (mm)	28.8 ± 12.1	35.4 ± 11.0	< 0.05
WS diam (mm)	5.22 ± 12.1	5.14 ± 0.55	ns
MLD pre (mm)	0.81 ± 0.52	0.80 ± 0.49	ns
MLD post (mm)	2.86 ± 0.56	2.42 ± 0.51	< 0.05
MLD fup (mm)	2.30 ± 0.59	0.91 ± 0.45	< 0.001
prox RD (mm)	3.45 ± 0.69	3.42 ± 0.50	ns
distal RD (mm)	3.04 ± 0.52	2.37 ± 0.57	< 0.001
WS diam/prox RD	1.56 ± 0.32	1.53 ± 0.27	ns
WS diam/distal RD	1.76 ± 0.36	2.27 ± 0.51	< 0.001

Lesion length, MLD post, distal vessel size and the degree of the oversizing of Wallstent (compared to distal vessel size) significantly related to greater luminal loss at fup. Diffuse long lesion in the small distal vessel may predispose to subsequent restenosis. Operators should avoid excessive oversizing in the selection of Wallstent and stenting in small distal vessel to lessen the risk of late restenosis.

973-69 Intra Coronary Ultra Sound Assessment of Balloon Angioplasty in Intrastent Restenosis

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Optimal treatment of restenosis occurring after coronary stenting, is not yet clear even if balloon angioplasty (PTCA) has been demonstrated safe and efficient. The mechanism of balloon angioplasty in intrastent restenosis was studied with Quantitative Coronary Angiography (QCA) and Intra Coronary Ultra Sound (ICUS) in 20 Pts. All Pts were dilated with a non compliant balloon inflated at high pressure (> 15 atm), QCA and ICUS data were available for all Pts at stent implantation (basal), before and after repeat (PTCA). Minimal Lumen Diameter (MLD) was assessed with QCA, and vessel size (EEM), stent cross sectional area, Lumen area and the neo intimal tissue area (Stent area - Lumen area) with ICUS.

	Basal	Before RePTCA	RePTCA
MLD (mm)	2.4 ± 0.5	0.7 ± 0.6	1.9 ± 0.7
EEM (mm ²)	12.9 ± 2.8	15.0 ± 3.7	15.9 ± 3.8
Stent area (mm ²)	7.1 ± 1.6	7.9 ± 2.0	8.5 ± 1.5
Lumen area (mm ²)	7.1 ± 1.6	3.2 ± 1.1	5.6 ± 1.0
Neo int tissue (mm ²)		3.9 ± 1.5	3.09 ± 1.6

Stent area increased after rePTCA, but most of the neointimal tissue remained within the stent thus explaining that despite stent overexpansion, MLD and Lumen area were lower after RePTCA than at initial stent implantation (respectively, 2.4 ± 0.5 vs 1.9 ± 0.7 mm, $p < 0.05$ and 7.1 ± 1.6 vs 5.6 ± 1.0 mm², $p < 0.01$).

We conclude that the mechanism of balloon angioplasty in intrastent restenosis is mainly overexpansion of the stent, most of the neointimal tissue remaining within the stent.

974 Glycoprotein IIb/IIIa Receptor Blockade

Tuesday, March 18, 1997, 9:00 a.m.-11:00 a.m.
Anaheim Convention Center, Hall E
Presentation Hour: 9:00 a.m.-10:00 a.m.

974-83 Addition of a Platelet Glycoprotein IIb/IIIa Inhibitor to Heparin + Aspirin Decreases Ex-Vivo Thrombus Formation After Percutaneous Coronary Intervention

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Although c7E3 Fab, a Gp IIb/IIIa inhibitor, decreases complications after PTCA, its effect on thrombus formation in these patients is unknown. To quantify the antithrombotic effects of standard dose c7E3 Fab, we studied 19 patients (60 ± 2 yrs, 75% men) undergoing coronary intervention using an ex-vivo perfusion chamber. Through a venous cannula, blood was pumped directly from the patient and circulated, under controlled rheologic conditions of high shear rate simulating mild arterial stenosis (1690 s^{-1}), through a chamber containing a standard thrombogenic substrate (injured porcine aortic media). Perfusion runs were performed on heparin + aspirin prior to the procedure in all patients and then repeated 2 hours after the procedure on aspirin + heparin alone (Group 1; $n = 10$) or on aspirin + heparin + c7E3 Fab (Group 2; $n = 9$). To quantify thrombus, chamber specimens were stained with trichrome and for fibrinogen and platelet factor 4. The cross-sectional area of the thrombus (TA; μm^2) was measured on 9 sections per chamber run with computerized planimetry. TA for each condition as mean \pm SE:

	Group 1	Group 2	p
TA preprocedure	12526 ± 1506	16575 ± 1566	NS
TA postprocedure	13953 ± 1510	8603 ± 930	0.04
p (within group)	NS	< 0.001	

There was no difference between groups in baseline Hct, platelet count, preprocedure PTT, and periprocedure ACT (291 ± 23 s).

Conclusion: The addition of c7E3 Fab to heparin + aspirin significantly decreases the propensity to form thrombus on an injured arterial surface, providing an insight into the mechanism by which c7E3 Fab reduces periprocedural complications.

974-84 Economic Assessment of Platelet Glycoprotein IIb/IIIa Receptor Blockade During Coronary Intervention in the EPILOG Trial

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In the 2099 pt EPIC trial, use of abciximab (c7E3 Fab, ReoPro) during coronary intervention decreased baseline hospitalization cost associated with ischemic complications, but savings were offset by costs of increased bleeding complications. The subsequent EPILOG trial demonstrated in 2792 pts that hemorrhagic risk associated with abciximab therapy can be nearly eliminated by reduction of heparin dosing. Using the Economic Model and cost data derived from the EPIC trial, in-hospital costs of treatment with abciximab in the EPILOG trial were estimated.

	EPIC (observed \$)		EPILOG (estimated \$)	
	Placebo	Abciximab	Placebo	Abciximab
Ischemic Events	15.4%	12.9%	13.9%	8.0%
Urgent CABG	3.6%	2.4%	1.7%	0.4%
Major Bleed	3.3%	10.6%	1.1%	1.1%
Baseline Cost	\$13,434	\$13,577	\$12,787	\$12,260
Abciximab Cost	-	\$1407	-	\$1407
In-Hosp Cost	\$13,434	\$14,984	\$12,787	\$13,667
In-Hosp Difference		\$1550		\$880
F/U Difference		(\$1270) savings		pending
Total Cost per pt		\$280		pending

In-hospital costs of abciximab therapy are approximately halved by control of bleeding risk. Thus, with the heparin regimen from EPILOG, initial data suggest that abciximab may incur sufficient cost savings over 6 months to pay for itself. Complete prospectively-collected in-hospital and 6-month medical cost data from EPILOG will be presented.